UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875** **HON. ROBERT B. KUGLER** **CIVIL NO. 19-2875 (RBK)**
THIS DOCUMENT RELATES TO ALL CASES	

PLAINTIFFS' BRIEF IN OPPOSITION TO ZHP DEFENDANTS' SUPPLEMENTAL MOTION FOR SUMMARY JUDGMENT

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PRELIMINARY STATEMENT

The ZHP Defendants' motion for summary judgment relies on misrepresentations as to their operations and conduct in this case, contrary to their own documents and admissions by their own witnesses. When the correct facts are seen in context of the law, analysis of the motions further demonstrates that Plaintiffs are entitled to partial summary judgment on the three issues advanced.

ARGUMENT

I.

ZHP AND HUAHAI GAVE EXPRESS WARRANTIES

ZHP inexplicably argues, "Plaintiffs' claims against ZHP and Huahai are barred because there is no evidence that either entity manufactured or sold any finished-dose VCDs." (ECF 2564-1, p. 1). The upshot of this argument is that if ZHP did not manufacture or sell the contaminated drugs, it could not have given any warranties. The entire factual premise of the argument is wrong, and the motion should be denied.

First, ZHP **is** the manufacturer of all of the contaminated valsartan API that adulterated all of the finished dose pills of all the defendants, and manufactured all of the contaminated finished dose (FD) VCDs containing the contaminated API that passed through ZHP's U.S. subsidiaries to the US market. (Pls.' Opp. to Defs.' SOMF ¶ 3; Pls. Affirmative SOMF ¶ 106, 164-167). In that capacity, ZHP prepared

and approved all artwork, inserts, labeling and packaging materials, and packaged/labeled all of the FD VCDs at ZHP's facility in China itself—with the Prinston/Solco packaging. (*Id.*). The packaging and labeling stated that the VCDs were FDA approved, USP compliant, and AB rated in the Orange Book, meaning it was therapeutically equivalent to the RLDs. (*Id.* at ¶ 92) ZHP then sold or transferred the finished dose pills to Prinston and Solco for distribution and sale in the United States. (*Id.* at ¶ 3). In fact, the ZHP Defendants' Drug Catalog for the FD VCDs prominently shows ZHP's, Huahai's,[1] Prinston's, and Solco's logos. (*Id.*).

In addition, Huahai was ZHP's U.S. Agent including for purposes of filing and maintaining the DMF, which is one of the sources of the representations constituting the warranties at issue here since ZHP represented to the rest of the downstream supply chain that its API was US DMF compliant. (Pls.' Affirmative ZHP SOMF ¶ 7, 146, 154, 162-63).[2] Of note, the DMF regarding the new zinc chloride manufacturing process falsely warranted that "there was not any high potency genotoxic group, such as N-nitroso compounds," in the valsartan API, when in fact there was NDMA in the valsartan. (Pls.' Opp. to Defs.' SOMF ¶ 83). The

[1] Notably, Huahai shares the same logo as ZHP. (*Id.*).
[2] ZHP ignores the warranties to its API purchasers, which were intended to flow downstream, including those provided to Teva and Torrent, and via the DMF and ANDAs. (Pls.' Affirmative ZHP SOMF ¶ 146, 154-154.5).

DMF for the TEA with sodium nitrite quenching process also contained this affirmative misrepresentation. (*Id.*).

The representations from ZHP were unquestionably directed at the purchasers of the VCDs, meeting even the ZHP Defendants' proffered standard. (ECF 2564-1, p. 3-4 (stating "While most of the jurisdictions at issue in subclass b have relaxed the privity requirement for express warranty claims, they still require evidence that the defendant made an express warranty ***that was directed at the purchaser***.")). ZHP strategically ignores the fact that its direct representations to customers, and representations via the DMF, ANDAs, and the USP and Orange Book—and most fundamentally selling the contaminated API and FD as "valsartan"—were what allowed the valsartan to be sold all the way down the supply chain to the point where a purchase was authorized and made in part by the TPPs. *In re Valsartan, Losartan, Irbesartan Prods. Liab. Litig.*, MDL No. 2875 (RBK-JS), 2021 WL 222776, at *11 (D.N.J. Jan. 22, 2021) (emphasis added) (ECF 775). (Pls. Omnibus Opp. to Defs.' Summary Judgment Mot., p. 5-26).

In addition, ZHP's eleventh hour effort to paint its wholly owned subsidiaries as materially separate should be rejected out of hand. The reality is that the ZHP entities are intertwined under the control of ZHP, and ZHP marketed and sold FD VCDs via its United States subsidiaries, including its agent for purposes of the filing of the DMF, Huahai US. (Pls.' Opp. to Defs.' SOMF ¶ 3). Among other relevant

facts on this point, in terms of control, Jun Du was the Vice Chairman of ZHP's Board of Directors and at the same time was the CEO of Huahai, Prinston, and Solco, during the relevant time period. (*Id.*). And ZHP's CEO Baohua Chen—who refused to appear for his Court-ordered deposition—maintained close control over the marketing and sale of the FD VCDs. This included the setting of prices. (*Id.*). There is consequently no practical distinction between the ZHP Defendants with respect to the marketing and sale of the VCDs—and most important, all were involved in providing the warranties at issue.

II.

ZHP'S VCDS WERE ADULTERATED

The ZHP Defendants argue that "the FDA has the sole authority to declare a medication adulterated and has never done so with respect to any VCD manufactured by [Prinston and Solco]." (ECF 2564-1, p. 1). This is an illogical starting point since Prinston and Solco did not manufacture any VCDs in this case—ZHP manufactured all of the API and finished dose sold by the ZHP Defendants. Virtually ignored by ZHP, the FDA definitively found that ZHP's valsartan was adulterated and barred it from importing any drugs from the offending facility until it could demonstrate that the extensive cGMP violations were sufficiently remediated, which took nearly three years. (Pls.' Opp. to Defs.' SOMF ¶ 17).

Aside from the misstatements in ZHP's motion as to what occurred, ZHP's attempt to limit the FDA's adulteration finding to the API is absurd. A pill containing adulterated API is adulterated by definition. 21 U.S.C. §. 351(a)(2)(B), (b) (stating: A drug … shall be deemed to be adulterated … if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess … [or] [i]f it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium."). The adulterated API in the finished dose is why the pills were required to be recalled, and this is why Prinston and Solco issued press releases stating that the recall was due to the "unacceptable carcinogenic risk to the intended patient population." (Pls.' Opp. to Defs.' SOMF ¶ 79, 125). In fact, ZHP told the FDA that the contamination levels measured in the API should be applied to the finished dose since the NDMA/NDEA contamination was the result of a manufacturing "process impurity" that contaminated the API and carried over to the finished dose when the API was included in the pills. (Pls.' Affirmative ZHP SOMF ¶ 28). ZHP has admitted that it

would be "unacceptable and unethical" to sell valsartan with those levels of NDMA contamination. (*Id.* at 139, 163.1). And that the FDA determined that the levels of NDMA in the valsartan "were not acceptable" from a health standpoint. Pls.' Opp. to Defs.' SOMF ¶ 79).

Taken to its illogical conclusion, if ZHP's argument were correct, pharmaceutical companies could "wash" any adulterated API by incorporating it into FD, a result that would render a finding that API is adulterated meaningless since all API reaches patients as the key part of finished dose pills.

The ZHP Defendants rely on a single trial court case for the proposition that "'adulteration' and 'misbranding' are regulatory classifications that are imposed solely by the FDA[,] not issues of fact for a jury to decide de novo." (ECF 2564-1, p. 6 (citing *Healthpoint, Ltd. v. Stratus Pharms., Inc.*, 273 F. Supp. 2d 769, 787 (W.D. Tex. 2001)). First, the FDA affirmatively did this in its November 29, 2018 Warning Letter based on significant cGMP violations leading to the nitrosamine contamination of their VCDs. (Pls.' Opp. to Defs.' SOMF ¶ 61).[3] Moreover, *Healthpoint* only concerned the plaintiff's request for "preliminary injunctive relief," in a very different factual context. This Court clearly can find here that the statutory definition of adulteration was met as a matter of law due to the NDMA and

[3] In addition, the FDA told Torrent that its contaminated finished dose was adulterated. (Pls.' Opp. to Defs.' SOMF ¶ 95, 96, 101).

NDEA contamination of the API and FD sold by ZHP. *United States of America v. 286,161 Bottles et al.*, No. 19cv3876, 2021 WL 2272402, at *3-4 (N.D. Ill. May 4, 2021); *Alra Labs. v. Am. Cyanamid Co.*, No. 92cv2252, 1996 WL 377070, at *4-5 (N.D. Ill. July 2, 1996).

III.

THE JULY 27, 2017 EMAIL PROVES SCIENTER FOR PLAINTIFFS' FRAUD CLAIMS

The ZHP Defendants' own 30(b)(6) witness confirmed what the July 27, 2017 email, sent by a Ph.D chemist under his supervision who was responsible for the identification of impurities and their root causes, to numerous high level ZHP employees, states:

> Through the secondary mass spectrometry analysis, it can be inferred that the extra NO substituent is in the cyclic compound fragment, and it is very likely that it is an N-NO compound; **it is similar to the N-nitrosodimethylamine that occurs in valsartan when quenched with sodium nitrite, and its structure is very toxic.**
>
> * * *
>
> **If it is confirmed as the above speculated structure, then its toxicity will be very strong, and there will be an extremely high GMP risk**. **This is a common problem in the production and synthesis of sartan APIs**. **It is recommended** to improve other quenching processes (such as NaClO) along with **the optimization of the valsartan sodium azide quenching process.**

(Pls.' Affirmative ZHP SOMF ¶ 40; *see also id.* at ¶ 35-42.5).[4] The language of this email is unequivocal, and Min Li's testimony that [redacted] both absurd and unavailing. (Pls.' Opp. to Defs.' SOMF ¶ 54).

The ZHP Defendants cite two cases. The first—*In re TMJ Implants Prods. Liab. Litig.*, 880 F. Supp. 1311, 1317 (D. Minn. 1995)—is inapposite even according to their own parenthetical, which states the plaintiff there "offered no evidence of defendant's knowledge of the danger." (ECF 2564-1, p. 7). **The July 27, 2017 email confirmed that there was NDMA in valsartan, and that the root cause was the quenching with sodium nitrite**, among other things. (Pls.' Affirmative ZHP SOMF ¶ 40). The relevant people at ZHP—who received the email—were thus aware of the issue along with the company scientist who sent it, and certainly others.

Second, the ZHP Defendants cite *Tershakovec v. Ford Motor Co.*, 546 F. Supp. 3d 1348, 1364-65 (S.D. Fla. 2021), for the idea that a court should grant "summary judgment on omission-based fraud claims for lack of scienter where alleged knowledge was premised on one internal email." (ECF 2564-1, p. 9). First, in this case ZHP affirmatively misrepresented that its valsartan met the requirements

[4] The ZHP Defendants' reliance on FDA statements regarding the foreseeability of the nitrosamine contamination are unavailing because ZHP never gave the FDA the July 27, 2017 email, and in those statements the FDA made clear that ZHP was at fault for its failures. (Pls.' Opp. to Defs.' SOMF ¶ 61; (Pls.' Affirmative ZHP SOMF ¶ 40-42.5). The FDA explicitly found that ZHP's risk assessment was inadequate and that ZHP was required to identify and address all impurities when it developed the new manufacturing process. (Pls.' Opp. to Defs.' SOMF ¶ 61).

of the FDA approval, DMF description, and complied with the compendial specifications. And the case concerned whether a single customer complaint put the defendant on notice of a potential defect. *Tershakovec*, 546 F. Supp. 3d at1364-65. Here, we have an internal smoking gun email written by a trusted scientist confirming knowledge of the existence and root cause for the creation of a genotoxic probable human carcinogen within the ICH cohort of concern, contaminating a drug the company was actively selling as within all quality and purity specifications. As set forth in Plaintiffs' affirmative motion for partial summary judgment on this claim, the Court should grant Plaintiffs' motion for partial summary judgment on liability for fraud.[5]

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[5] The ZHP Defendants include a series of mischaracterizations regarding Plaintiffs' chemistry experts in this section of their brief. (ECF 2564-1, p. 7-10). Those experts' opinions are unnecessary to prove the ZHP Defendants' liability for fraud at least from July 27, 2017 onwards. In fact, the email was produced under suspicious circumstances (a pdf, and none of the other recipients were listed as duplicate custodians). The ZHP Defendants have never produced Jinsheng Lin's investigation into the creation of NDMA in valsartan quenched with sodium nitrite, and this supports Plaintiffs' experts who all agree that rudimentary knowledge of chemistry, at least for a pharmaceutical chemist developing a manufacturing process, should have alerted ZHP to the issue, *i.e.*, there really is no need for sophisticated chemistry research and analysis to know that known impurities/degradation products of DMF and TEA, and TEA itself, will potentially create nitrosamines when quenched with sodium nitrite. Plaintiffs address the ZHP Defendants' mischaracterizations in Paragraphs 58, 59, and 66 of their Opposition to Defendants Statement of Material Facts. It is nevertheless worth noting that the ZHP Defendants rely on Paragraph 66 of their Statement of Material Facts regarding the July 27, 2017 email, but that paragraph focuses on Dr. Fengtian Xue's absurd ipse dixit opinions regarding the email, which the Court properly precluded from reaching a jury, along with the rest of his substantive opinions seeking to exonerate the ZHP Defendants. (ECF. 2571,

CONCLUSION

For the foregoing reasons, the Court should deny the ZHP Defendants' motion for summary judgment.

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